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# Thoughts on Commercialising MedTech

## How to Improve Your Chances of Success

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"It has been estimated that the Australian MedTech industry grosses over ten billion dollars annually[1]. This is attributed to the relatively small number of companies that are successful in commercialising their products in comparison to all companies that start with a bright idea. Many, possibly as many as 90% of innovations, will fail[2].

This paper examines some of the most common reasons for this failure, and suggests some strategies to increase your chances of success in this complex and rewarding field.

AusBiotech, Australia's peak body representing the biotechnology industry, sees Medical Technology as a vital biotech sector, alongside Pharmaceuticals, and Food and Agriculture. AusBiotech describes medical technology, or "MedTech" for short, as follows:

*Medical technology (MedTech) refers to medical devices and diagnostics, including in vitro diagnostics (IVDs). The Therapeutic Goods Administration (TGA) describes medical devices as having therapeutic benefits, which either affect the body in a physical way or are used to measure or monitor functions of the body. Examples of medical devices include artificial hips, blood pressure monitors and orthodontics.*

MedTech Europe has a similar definition:
*Medical technology is any technology used to save lives or transform the health of individuals suffering from a wide range of conditions. In its many forms, medical technology is already diagnosing, monitoring and treating virtually every disease or condition that affects us…medical technology includes medical devices and in vitro diagnostic medical devices.*
*Medical devices are products intended to perform a therapeutic or diagnostic action on human beings by physical means.*
*In vitro diagnostic medical devices are products which provide medically useful diagnostic information by examination of a specimen derived from the human body.*

In the 2019 industry snapshot, AusBiotech noted the following about the MedTech sector:

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[1] https://www.informa.com.au/insight/commercialising-healthcare-innovation/

[2] https://fortune.com/2014/10/07/innovation-failure/

- There are 387 medical device and digital health companies in Australia, of whom 314 (81%) are SMEs
- The majority (75%) of these companies are based in NSW and Victoria
- 67 of these companies are listed on the ASX, making the MedTech sector the majority of life science companies on the ASX.

The following issues are potential causes of MedTech business failure. Each one on its own may not be fatal, but the more of these issues that are present and not dealt with the harder it is for a business to succeed. Following are some suggestions as to how to address these issues should they arise.

**Lack of money.**
This is an obvious reason why MedTech companies fail to get their bright idea to market. There are many different reasons why this happens, however. Overcoming the following more fundamental problems will hopefully prevent this situation occurring:

**Failure to articulate the value proposition.**

There is a lot of money out there for the "right" innovation, but the investors who have the money need to understand why the customer will buy your product. There is often a large disconnect between what value and attraction the inventor places on an innovation, and that placed on it by the end user. When customers face choices, they base their decisions on the relative perceived value, not the actual or economic value, of the new product. And a big factor in this is that most people are reluctant to change what they are doing, unless there is a compelling reason to do so. How well innovators understand and articulate that compelling reason will influence how likely investors are to put their money in. How do you convince an investor that you know that the customer will buy your product? You have to have gone out and asked the customer. But that means you have to know who they are.

**Failure to understand who the customer is.**
In MedTech, the customer could be the clinician (pathologist, orthopaedic surgeon, GP, etc), or the customer could be the ultimate end user – the patient, or the customer could be the insurer or the government. What motivates each of these users is very different, so whilst a device may appeal to a clinician because it makes a procedure easier, the patient may not want to pay the premium for it. So, when an investor asks who is the customer, a successful innovator will not only know who the customer is, but will also know why they will buy the product.

**Failure to understand what the customer values**
I know Steve Jobs famously said "*Some people say, "Give the customers what they want." But that's not my approach. Our job is to figure out what they're going to want before they do. I think Henry Ford once said, "If I'd asked customers what they wanted, they would have told me, 'A faster horse!'*" In Jobs' case, he knew exactly who his customer was and was not (the customer was not a computer specialist. The customers were those who wanted to do everyday tasks faster and easier, and who had never bought a computer before). He had a very clear vision and a great feel for the end user. In MedTech, it is unlikely that your innovation will be a mass consumer item. It will be used by or for people who are suffering from a disease of other medical condition, or who want to avoid suffering from a disease or condition. So, what the end user values is something that they can rely on to improve their lives, and be willing to pay for that. The medical specialist who may be the customer does not want to compromise the patient's health, so they need to be convinced that the innovation will either improve the outcome for the patient, or will provide the same outcome but for a lower price, or faster, or less painfully. The government

values the cost savings that the innovation will bring to the health budget. The more indirect these benefits are, the harder it will be to convince a customer to pay for it.

Having determined who your customer is and what is likely to drive their decision based on the value they are looking for, the next thing to do is to get some evidence to support this. This is where "Voice of Customer" typically comes in. "The Voice of the Customer is a process for capturing customers' requirements. It produces a detailed set of customer wants and needs which are organized into a hierarchical structure, and then prioritized in terms of relative importance and satisfaction with current alternatives"[3]. But caution is required here. If it is done correctly, with the correct customer/end user, then "it can form a solid basis for design and marketing decisions from concept development through product launch". If done badly and/or if the results are seen as absolute, it can doom the product even before it is launched. It must capture what the customer/ end user values and what would make them change from what they are doing currently. Remember the 2019 Australian Federal election result, or the 2017 US Election result. The polls in both elections got the wrong result. The "Voice of Customer" – in this case the Opinion Polls - was wide of the mark. Why? Because the voters changed their minds on the day. Or they gave one answer in a hypothetical situation, but when it really counted – election day – they realised the implications of what they were doing and many of them changed their choice. The same danger potentially lurks in Voice of Customer surveys. There is a big difference in hypothetically spending an extra $100 on a more accurate blood pressure monitor, and in actually handing the money over. That is the moment when the value proposition is really considered.

**Failure to understand the customer's barriers to change**

Whilst your potential customers may see the value in your innovative new product, they may simply be constrained by an inability to change for external reasons that have nothing to do with you or your product, and over which you may have little control. Failure to understand these barriers and how long they may take to overcome can seriously impact cash flow projections, with obvious consequences for the business. There may not be any approved reimbursement codes available (this can take up to two years in the US). Healthcare customers (clinicians, hospitals, laboratories) may be locked into business models that depend upon patients accessing existing products. Companies need to do a thorough stakeholder review to identify these hurdles to adoption and ensure key revenue projections are based on solid data.

**Failure to provide an actionable clinical benefit.**

Let's imagine that you have developed a non-invasive, 99% accurate, scalable, and inexpensive diagnostic test that no-one else has, for a widespread neurological disease. Fantastic, right? There has to be a market for it! So, you lodge a provisional patent, then persuade friends and family to invest $50,000 to develop it. In your first investor presentation, you are asked the following question. "It looks like a great invention, but currently, there is no cure, or even a treatment for this disease. What does the patient or the clinician do with the knowledge that they have the disease in its early stages?" Telling a patient that they have an incurable and progressive fatal disease without treatment options has a number of positive and negative implications that will potentially devalue the test in the eyes of both the clinician and the patient. So, developing a technology without carefully considering the wider clinical context can result in failure. To quote Bronwyn Le Grice (founder of AND Health): *"It's all about right information, to the right people at the right time [with the aim of transforming] prevention, diagnosis, treatment and care."*[4]

**Starting without the end in mind.**

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[3] http://www.mit.edu/~hauser/Papers/Gaskin_Griffin_Hauser_et_al%20VOC%20Encyclopedia%202011.pdf

[4] https://www.informa.com.au/insight/commercialising-healthcare-innovation/

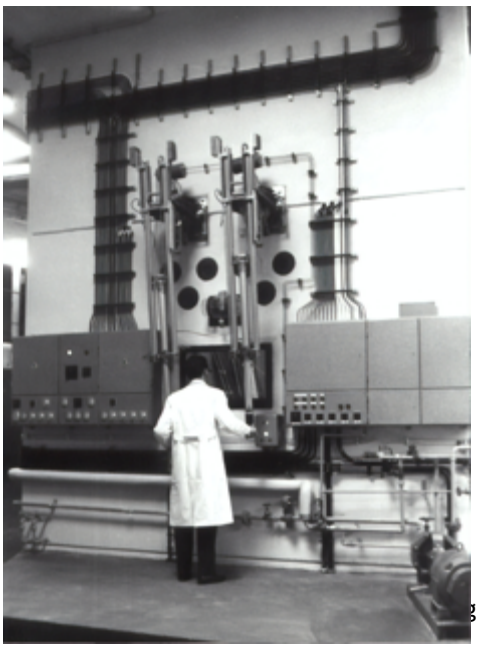
One of Stephen Covey's "7 Habits of Highly Successful People" that really resonates with me is to "start with the end in mind". This applies absolutely to MedTech innovations. Data generated by laboratory-grade reagents or laboratory-scale processes will need to be re-done using the planned final configuration before a regulatory body such as the FDA will approve your innovation. This means that any and all of the technical data to support how well your device works, or how safe it is, that doesn't utilise the processes and materials of the proposed product being launched on the market will, in all likelihood, be unusable for regulatory submissions. In some cases that might just be the cost of developing and prototyping and tweaking the innovation, and that's fine. As long as you and the investors understand that, and factor that into the budget and time expectations. But going to the regulator with sub-optimal data is a very expensive and time-consuming mistake that can be the kiss of death for a start-up. In a similar vein…

**Changing design or integral components during development.**
If you tinker with the design after you have generated key data to verify and validate the product's performance you will have to go and do it all over again on the new product. This is very costly in terms of time and money. Unless the design changes lead to a vastly and significantly better product, it would be much more sensible to go to the market with your first generation product while saving the improvements for the next model – Mark 2.

**It doesn't work.**
The best advice is to find that out as soon as possible, and move on. Don't keep trying to flog a dead horse. If you are licensing the innovation in from an external source, be sure that the data can be reproduced independently. It has been reported by industry It is reported that, in the field of cancer research, only 11-25% of published studies could be validated or reproduced independently[5,6]. Sometimes a small sample size can produce encouraging results that cannot be reproduced in larger cohorts. Or technologies that work very well in vitro fail to produce the same results when translated into people. It is important to know when to close down a program or project for lack of efficacy.

**It works great – but nobody needs it.**
As early as possible in the development of the device – but ideally after lodging the patent application – you should validate your assumptions about the need for the product with clinicians and/or patients. This will also help to overcome scepticism from potential investors. Even if they need it, will they need it enough to buy it over what they are currently doing?

**It's late to market.**
This is not necessarily the death knell for an innovation. Best to market will usually beat first to market. In fact, the first product to market can encourage the target customer to be more receptive to change, and if and when a better, more attractive, less painful, more accurate product comes along, the customer is already understanding the value proposition and will be open to change. But if your innovation is a "me too" product, without a compelling value proposition or benefit, then it is unlikely to be successful. So, speed to market is important, but value proposition is more so, so take your time and get it right, if you have a truly innovative and differentiated product.



**It will be obsolete soon.**
Be aware of the industry trends and ensure you do not have a solution for s problem that will be gone soon because of changing technology in the broader field. If in

[5] Prinz F, Schlange T, Asadullah K. Believe it or not: how much can targets? *Nat Rev Drug Discov* 2011; 10(9):712.

[6] Begley CG, Ellis LM. Drug development: raise standards for preclinical cancer research. *Nature* 2012; 483:531–3.

1899 you had invented a glue that could save blacksmiths from having to nail horseshoes onto horses' hooves, it may have seemed like a great idea with a huge market. Unless you were aware of Henry Ford's invention that would revolutionise transport and inevitably make horse-drawn transport obsolete.

**You have the wrong team.**

In my opinion, a successful innovation needs a team that comprises:

- A visionary leader to think beyond the here and now to what might be
- A technically proficient and rigorous scientist/engineer
- An experienced regulatory professional
- A highly competent and charismatic operations manager to pull all the disparate activities together
- An extensive network that can be called upon to help when faced with a potentially insurmountable hurdle

Sometimes, they are all the same person. But not often. Alfred Lo, formerly of Sydney's Cicada Innovations commented, "Great things come when you bring people together from different skills and experience – strong commercial and strategic thinkers combined with researchers and scientists working on breakthrough technologies – that's when you see really successful innovation".

**Overpromising and under delivering.**

It's an easy trap to fall into. Promised deliverables will be remembered and held against you. Are the costs and timelines that you are estimating to take a device to market possible, or even likely? Are the market penetration rates and revenues likely? Obviously, there is a fine line to tread here. You should aim to give a range – best and worst-case scenarios, and the middle range. If the worst-case scenario means you don't get as much funding, then it probably tells you that it is going to be a difficult journey. MedTech innovations usually require long time frames and patient capital before realising projected revenues. This is due to a number of factors, some of which are well understood by investors and innovators, and some less so. The time to recruit patients and undertake clinical trials can vary widely depending upon the prevalence of the condition being addressed, the current state of care, the potential risks of the intervention, and so on. Complex regulatory, reimbursement and procurement pathways require considerable evidence-based data to be collected, and that can be time consuming. It is important for all stakeholders to understand these constraints on MedTech innovation. Innovators should be cautious about engaging with investors who don't understand the potential time horizons and are looking for a quick exit. This pressure can cause companies to cut corners, to the long-term detriment of bringing the product to market. Be careful that you can deliver on your promise. On example is seen in off-label use of products. Many MedTech companies imply, or factor into their market size estimates, off-label use for their product. However, a company can't market a product for off-label use, and this results in projections based on this application be overestimated.

**Underestimating the risks.**

Write down EVERY risk you can think of. And then write down some more. The World Economic Forum did not have a pandemic threat in its top 20 risks in its 2020 Global Risks Report. COVID-19 rendered that report irrelevant by February. Factor the risks into your estimated time and cost to market entry and return on investment, and your business model. And formulate mitigation strategies to deal with the risks should they arise.

A major risk is the time needed to get regulatory approval for use of the product, which leads to…

**Underestimating the regulatory hurdles.**
Innovators, especially inexperienced Australian innovators, often do not have sufficient knowledge of the USFDA or even the TGA regulatory approval application process. There are a number of paths to FDA clearance or approval. For example, you may have to decide between a de novo, a PMA, a BLA, or a 510(k). Is there an appropriate predicate device? If you underestimate what it takes to get market approval, you'll lose credibility with supporters and investors. Ensure you understand early on what the requirements are that you need to address in your documentation, and plan accordingly.

**Partnering too early.**
There are many benefits of early engagement with potential clinical and commercial partners. By talking to multiple interested parties, competitive tension can be built, insights into what the market wants to see can be gained and further opportunities for your innovation could be identified. However, you usually only get one shot at this, so trying to partner too early with a product or service that is sub-optimal can cruel your chances of getting the partnership then and later. Also, first impressions are important, as is word of mouth and reputation. All are hard won and easily lost. It is a judgment call, but I would prefer to impress a potential partner with a compelling semi-finished beautiful swan than going in with an ugly duckling that may have the potential to turn into a beauty.

**Lack of documentation and record-keeping.**
Essentially, there is just one message to know here - if it isn't properly documented, it didn't happen. The earlier a company understands what needs to be documented and how to document it, the greater the chances are that its development efforts will pay off when it comes to overcoming regulatory obstacles and getting a product onto the market.

**Being too ambitious**

Ensure that your resources match your plans to target the channels for your device. It's best to map out your channels in order of priority and ease of market entry, identify the early adopters for each and the likely potential sales volume per channel, and then devise strategies to enter those channels sequentially, starting with the easiest. This may not be the most lucrative channel, but a staged approach gives you the opportunity to get a few wins, build cash and a reputation, and, importantly, to make tweaks depending upon market feedback. It also allows you to build inventory without an enormous cash outlay upfront. Trying to enter all channels simultaneously can mean that you won't be able to service all equally, and you will end up disappointing some, or all, of your potential customers. Hasten slowly.

**Not being ambitious enough**
Whilst it may be sensible to start small and local, and revenues that result may be sufficient to sustain a comfortable but small business, if your product is truly innovative, plan to expand it outside your comfort zone so that it can benefit a wider range of patients. This will also have the benefit of expanding your business into a successful enterprise and provide investors with a solid return on their investment.

**Final Thoughts**
Remember that the road to success is beset by pitfalls and hurdles, no matter how great the underlying science may be. You should aim to control as much as you can during the development phase of your MedTech product to maximize the chances of its success, increase the value of your product and company, and most importantly, to bring your product to market to improve patients' lives and health. Good luck!